

EXHIBIT D

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A., INC.)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 13-cv-1729-SLR
)	
AMNEAL PHARMACEUTICALS, LLC,)	
)	
)	
Defendant.)	

**PLAINTIFF'S FIRST SET OF INTERROGATORIES
TO AMNEAL PHARMACEUTICALS, LLC**

Pursuant to Federal Rules of Civil Procedure 26 and 33, Plaintiff Takeda Pharmaceuticals U.S.A., Inc., requests that Defendant Amneal Pharmaceuticals, LLC answer the following Interrogatories in writing and under oath within thirty (30) days of service of these Interrogatories or at such other times and places as the parties may agree or the Court may order.

INSTRUCTIONS

A. Each response shall include such information as is within your custody, possession or control or that of your attorneys, investigators, agents, employees, or other representatives.

B. If, after exercising due diligence to secure the information requested, an Interrogatory or any part thereof cannot be answered fully, please state the reasons for the inability to answer fully, answer the Interrogatory to the fullest extent possible, and state what information, knowledge, or belief you have concerning the unanswered portion.

C. For any information withheld on claim of privilege or work product, provide a written statement setting forth:

(1) The identity of each person from and to whom the information has been communicated;

(2) A brief description of the subject matter of the information; and

(3) The privilege relied upon in withholding the information.

D. If, after answering these Interrogatories, you learn additional information that makes any of your previous answers incomplete or inaccurate, then you must serve supplemental answers correcting and updating your prior answers. Supplemental answers must be completed and served as soon as possible after you learn of such additional information.

DEFINITIONS

As used in these Interrogatories, the following terms have the meanings indicated below:

A. “Amneal” means defendant Amneal Pharmaceuticals, LLC and every present and former officer, director, managing agent, employee, attorney, consultant, expert, and all other persons purporting to act on behalf of Amneal Pharmaceuticals, LLC, or their corporate predecessors.

B. “You” or “your” refers to Amneal, as defined above.

C. “Takeda” means Takeda Pharmaceuticals U.S.A., Inc.

D. “Amneal Proposed Product” means any single active ingredient colchicine product for which Amneal (as defined above) has sought FDA approval to market and sell.

E. “FMF Paragraph IV Letter” means the written notification to Takeda Pharmaceuticals U.S.A., Inc. dated September 9, 2013.

F. “Patents-in-suit” means U.S. Patent No. 7,906,519, U.S. Patent No. 7,935,731, U.S. Patent No. 7,964,648, U.S. Patent No. 8,093,297, and U.S. Patent No. 8,093,298.

G. “Identify” means:

(1) In the context of a natural person, to provide the person's (i) full name; (ii) present or last known residential address and telephone number; (iii) present or last known business address and telephone number; and (iv) present or last known place of employment and job description. If the natural person was employed at Amneal or any Amneal Entity as defined above, "identify" also means to provide (v) the title(s) of the person and the person's dates of employment. Once a person has been identified in accordance with this paragraph, only the name of that person need be listed in response to subsequent Interrogatories requiring identification of that person.

(2) In the case of a business, legal, or governmental entity or association, to provide the entity or association's (i) full name; (ii) legal form (i.e., corporation, partnership, etc.) and state of incorporation or legal formation; (iii) address and principal place of business; (iv) officers and other persons having knowledge of the matter with respect to which the entity or association is named; and (v) the basis for its inclusion in your response.

(3) In the case of a document, to provide: (i) the identity of the person(s) originating and preparing it; (ii) the sender, if not the person who originated it; (iii) its general type (e.g., letter, memorandum, etc.), title, and identifying number; (iv) the general nature of its subject matter; (v) its date of preparation; (vi) the date and manner of any transmission, distribution or publication; (vii) the location of each copy (including title, index number and location of the file in which it is kept or from which it was removed) and the identity of the present custodian or persons responsible for its filing or other disposition; and (viii) the identity of persons who can authenticate or identify it.

(4) In the case of a thing, to provide: (i) any model or catalogue number; (ii) any article or model name; (iii) any technical or promotional materials describing the article or its use; and (iv) the dates and locations of its production.

(5) In the case of an oral communication or meeting, to provide: (i) the date of the conversation or meeting; (ii) the location where it occurred or, in the case of an electronic communication, the location of each party; (iii) all individuals who participated or were present; (iv) the substance of what was discussed; and (v) all actions taken as a result of the communication or meeting.

H. “Including” means “including without limitation.”

I. “Communication” means any transmittal of information (in the form of facts, ideas, inquiries or otherwise) by oral, written, telephonic, electronic or radio frequency transmission, or any other means.

J. “Document” is synonymous in meaning—and equal in scope—to the usage of this term in Federal Rule of Civil Procedure 34(a), and includes any electronic or computerized compilations. A draft or non-identical copy (including copies with stamps, initials, comments, notations or other markings) is considered a separate document within the meaning of this term. This definition specifically includes e-mail or other electronic communications.

K. “Concerning” means relating to, referring to, regarding, describing, evidencing, supporting, documenting, involving or constituting.

L. The connectives “and” and “or” shall be construed either disjunctively or conjunctively as necessary to bring within the scope of a discovery request all responses that might otherwise be construed to fall outside its scope.

M. The use of the singular form of any word includes the plural and vice versa.

N. Any pronoun shall be construed to refer to the masculine, feminine, or neutral gender, as appropriate.

INTERROGATORIES

INTERROGATORY NO. 1:

State the basis for Amneal's decision to carve out the gout indications from the Colcris® label including any financial, marketing, clinical, legal or other factors leading to Amneal's decision to seek FDA approval for the use of colchicine to treat Familial Mediterranean Fever and identify the Amneal employees most knowledgeable regarding Amneal's decision.

INTERROGATORY NO. 2:

For each Patent-in-suit that Amneal contends is invalid, describe each basis for Amneal's contention including: (1) the identification of each patent; (2) the identification of each claim; (3) the legal basis for Amneal's contention of invalidity; (4) each purported prior art reference Amneal relies upon to support its contention; (5) on a claim by claim limitation, all statements made in the prosecution history that Amneal's will rely upon to support its contention; (6) the identity of each Amneal employee that has factual information supporting Amneal's contentions, including the nature and extent of the information known to such person; and (7) all other facts, documents, and things that Amneal intends to rely upon to support its contentions.

INTERROGATORY NO. 3:

For each asserted claim of the Patents-in-suit that Par contends is not infringed, describe each basis for Amneal's non-infringement position including: (1) the identification of each claim that Amneal contends has not or will not be infringed; (2) for each such claim, separately identify each limitation that Amneal contends is absent in the Amneal's Proposed Product and proposed labeling; (3) separately for each such limitation, describe the complete factual basis and

evidentiary support for the absence of each such limitation both literally and under the doctrine of equivalents; (4) the identity of each Amneal employee that has factual information supporting Amneal's non-infringement contention, including the nature and extent of the information known to such person; and (5) all other facts, documents, and things that Amneal intends to rely upon to support its contention.

INTERROGATORY NO. 4:

Describe fully and with particularity the regulatory approval status of ANDA No. 204711 including: (1) whether FDA has granted tentative approval of ANDA No. 204711 pursuant to 21 C.F.R. § 314.105; (2) whether FDA has requested additional bioequivalence testing for Amneal's Proposed Product, and if so the status of any such testing; and (3) an identification of all documents related to FDA's evaluation of ANDA No. 204711.

INTERROGATORY NO. 5:

Identify each document relied upon by Amneal to support the positions set forth in Amneal's FMF Paragraph IV Letter and the Amneal employee most knowledgeable about the facts contained in the letter.

INTERROGATORY NO. 6:

Identify each document that demonstrates or supports Amneal's economic and/or financial analysis of the Familial Mediterranean Fever market, including Amneal's business plans, market analysis, and market impact/penetration analysis for its Proposed Product and identify the Amneal employee most knowledgeable about these facts.

INTERROGATORY NO. 7:

For each Interrogatory served by Takeda in this litigation, identify all persons who supplied information used in preparing Amneal's response to each interrogatory, and for each

person identified, state the nature and extent of the information provided by such person.

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Dated: January 3, 2014

CERTIFICATE OF SERVICE

I hereby certify that on the 3rd day of January, 2014, a true and correct copy of

PLAINTIFF'S FIRST SET OF INTERROGATORIES TO AMNEAL

PHARMACEUTICALS LLC was served on the following counsel via electronic mail:

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